User's Manual

of

SW-3304

Digital Electronic Colposcope

Introduction

Welcome to use our Digital Electronic Colposcope, We are greatly honored by your trust in this apparatus.

Please read this Using Guide carefully, it will help you to use the apparatus properly. The contents of this Using Guide are as follows: Instrument Characteristics, Structure and Technical Characteristics, Keyboard Operation Function, Operation Instruction, Trouble Shooting, Maintenance, Precautions, etc. **Please read all the data and information delivered together with the instrument carefully and pay special attention to the safety information and notices in the Manual before you start mounting and using it. These will help you to use this Instrument better.**

In addition, during use once you find the product unsatisfactory, please inform us of it by email or telephone or visit ours website, we will render wholehearted service to you.

Service Hotline: 86-516-82308605 / 82300323

Sanwe Website: **http://www.vvvmc.com**

Exemption Clause

Description in this Operation Manual does not represent any explanation for product specifications and its software and hardware allocations. For product specifications and its allocations, please read the related agreement and packing list.

During compiling of the Operational Manual, we strive for making its contents right and whole, but we do not guarantee that there are no any errors or oversights. Since the products and service of CARL NOVEL are continuously being optimized and improved, we reserve the right to modify our products and the contents of the Manual without notice. During using this product, if you find that the product does not conform to the contents in the Manual and want to obtain the last information or have questions or ideas, please contact us or visit ours website.

Limited Guarantee / Repair

We will provide after-sale service according to Standard Service Promise (Guarantee

Repair Content) enclosed with the product. Beyond Standard Service Promise we do not provide any services.

Under maximum lawful condition, Jiangsu Sanwe Medical Science and Technology Co.,ltd. is not responsible for following whichever clause in any situations:

1. The third party claims requirement on you (death and personal injury, but except fixed property and related tangible property);

2. The loss or damage of your record or data;

3. Special, incidental or indirect damage or whichever resulting economic demage (including the losses in profit and deposit), even if CARL NOVEL has been informed of the possibility of the damage and losses.

4. The failure caused by your mounting software or hardware which are not provided with the product. Through inspection the failure is not related to the Sanwe product.

5. The failure caused by the environment which is not determined by the Manual or by the operation method which is not determined by the Manual.

6. The product damage caused by force majeure.

The product information is available through helpline or on ours website.

Signs Explanation

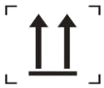
Note: Important information for proper product using.

Notice: Prompt information for possible product failure, property loss or personal injury

High voltage notice！Please consult the attachment file

Don’t discard into garbage cans directly.

“B” type equipment

 This side up Fragile

Caution against wet Keep away from heat

Pile Grounding Protection

Contents

Introduction----------1

Contents----------4

Chapter 1 General Outline----------5

1.1 Product characteristics----------5

1.2 Main purposes and suitable scope----------5

1.3 Normal work conditions----------6

1.4 Transportation and Storing----------6

1.5 Safety Standard and Requirement----------6

Chapter 2 Structure Characteristics and Work Principle----------6

2.1 Structure characteristic----------6

2.2 Operation part diagram of instrument----------7

2.3 Function of camera operating grip----------8

2.4 Working principle----------8

Chapter 3 Technical Characteristic----------8

3.1 Main Features----------8

3.2 Software Running Enviroment----------9

3.3 Performance Requirement----------9

3.4 Function Requirement----------9

Chapter 4 Installation----------10

Chapter 5 Operation Instruction----------11

5.1 Examination method----------11

5.2 All instruments and medicine needed for vagina inspecting----------11

Chapter 6 Precautions----------3

Chapter 7 Trouble shooting----------7.1

Checking----------14

7.2 Trouble shooting----------14

Chapter 8 Maintenance----------15

Chapter 9 After-sale service----------16

Chapter 1 General Outline

1.1 Product characteristics

The history of colposcope clinical application has already been more than 70 years, totally can divided to 4 stages. From the beginning of hand-hold optics magnifying glass, binocular vision optics colposcope, “electronic colposcope” to show vagina images on the monitor by camera, to the “digital electronic colposcope” which connected by digital camera system and computer image processing. The imaging quality, definition and operating methods of newfashioned colposcope have got great progress along with the never-ending changes and improvement of medicine diagnosis and medicine electronic imaging technology. Colposcope checking is of great value in vulva, vagina and cervix lesion checking, especially in cell fall out checking. It can be a very effective method of diagnosticate cervical carcinoma by using cytology checking act in concern with colposcope checking.

I4 Digital Electronic Colposcope is a low illuminance, high resolution camera. It is made up with self-developed facilities as： high illustration shining and no shadow lighting institution, high-speed computer image collection processing system, image analysis processing software package, colorful report printing output equipment, portable vertical bracket and luxurious trolley etc. It’s different from traditional colposcope checking for it has no ocular, and adopts DSP moving electronic focusing frozen controller. The superior light source and high power enlarged image can distinguish ultrafine details, so doctors only need to observe the focus image showed on the screen. Owing to all functions of this apparatus has been gathered in computer central control system, it make operation easier and can be used in diagnostic as well as in operation. Furthermore, the assorted computer image management system can analysis, process, save and print the observational images, which supply both doctors and patients a top-quality service.

1.2 Main usage and scope of application

This apparatus is mainly available for vulva and vagina checking, assist diagnosis for cervix disease and image management.

1.3 Normal working condition

1.Environment temperature: 5～35℃
2. Relative humidity: ≤80%；
3. **A**tmospheric pressure: 86 KPa～106 Kpa
4. Far away from magnetic field interference
5. Continuous working time: ≥8h
6. Service voltage: AC 220V±22v，50Hz±1Hz

1.4 Transportation and Storage

1.Environment temperature: -10℃～40℃
2. Relative humidity: ≤80%；
3. Service voltage: 50 KPa～106 kPa

1.5 Safety standard requirement

1. Conformity with GB9706.1-1995《 Medical Electric Installation Section 1: Safety claim》.

2. Use standard three-phase power source socket in the instrument room, connect its grounding terminal to protective earthed conductor of power supply system. Using the socket without protective grounding terminal, please adopt a metal conductor with cross area of not less than 1.0 mm2, connect one end of the conductor to ground pole and other end to earth.

Notice: Laying ground conductor shall be carried out according to related standard or under guide of experienced electrician.

Chapter 2 Structure Characteristics and Working Principle

2.1 Structure Characteristics

2.1.1 Basic configuration

Trolley with host computer: 1unit Colorful Monitor: 1 unit

Camera: 1unit Bracket: 1 unit

Printer: 1unit

2.1.2 Accessory

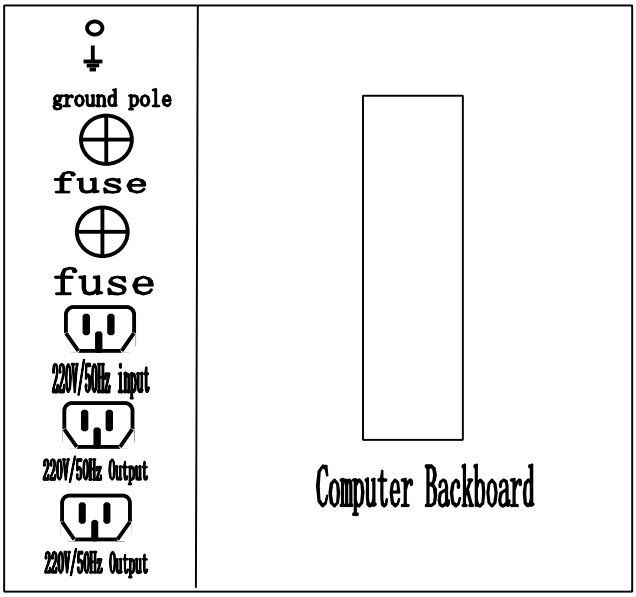
Packing information: 1 bag Control line: 1

2.2 Operation part diagram of instrument

2.2.1. Front looking

SW-3304数码电子阴道镜(高清专业版)

2.2.2 Backboard looking



2.2.3

Powe **r**

2.3 Instruction of the Keys on Camera and Remote Control

1). Aiming: adjust light intensity of video camera.
2). Fcs-F / Fcs-N: adjust distance of video camera focus (Far or near).
3). Enlarge / Reduce: enlarge or reduce moving images.
4). RL+/RL-: Increase or decrease red light on images.
5). Adjustment: White balance adjustment.

2.4 Working Principle

This apparatus uses general morphologic diagnostic method, to enlarge vagina

endocervicitis by high-resolution colorized video camera. After computer image processing, doctor can observe the changes of surface morphology and end-vasoganglion of endocervicitis so as to observe the minor pathological changes which can't be seen by naked-eye.

Chapter 3 Technical Characteristics

3.1 Main Technical Characteristics

Video camera lattice: 80, 0000 pixel high-resolution imported colorized CCD

4-64mm optics zoom lens

Minimum valid illumination: 0.1Lux

DSP dynamic automatic focusing system, equipped with manual focusing adjustment

18 x digital zooming, 16 x optics zooming, magnification times 128

Visual envelop: 2.5mm-20mm-320mm

Video camera resolution: ≥480TVL

3.2 SW-3300 Colposcope image processing software running environment and basic configuration

Microsoft windows XP operating system

1GB, DDR2 memory

160GB Hard disk space, can accommodate more than 30, 0000 case report.

Special medical pseudo-color capture card

24bit (real colorized), 1024×768 resolution

HP high-resolution color ink jet printer

3.3 Performance Requirement

Focal length is within 25cm-35cm, magnification times is 128

Focal point and focal length can be adjusted both by knob on camera head and computer.

Image capture quality 768×576 and can be reserved

3.4 Function Requirement

Please see below table

Style	Dynamic observation at real-time	Image processing	Records management	Building and edit of reports
SW-3303	Real-time dynamic observation, immediate image collecting , frozen, preserve and delete	Selected area can be enlarge , strengthen images, surface length measured，over turning in all sides, negative image, calibrate set up, imaging note and colored	Searching, add, amending delete and inquiry of case reports.	Reports can be added and chosen, you can edit anything and add pictures you need on printed report module.

Chapter 4 Installation

4.1 Host installation

Please reference to the Appendix – Guide of installation

- After unpacking, check all the parts according to packing list. Host computer and accessories shall be in conformity with packing list. Read this operation manual carefully and know using method of the instrument well.
- Take out host computer, printer, video camera, bracket and leads
- Fix video camera on the bracket, it needed to fix the minor liquid crystal on the bracket if it's style 3304.
- Connect host computer, monitor, printer and keyboard.
- Insert the S-video terminal to the capture card on the back of host computer. Insert the D type nine-pins of control line to console serial port. Insert the nine-heads contact pin to the corresponding D type jack (DC 12V).
- Insert the D type 15-pins of video camera to D type 15-pins jack, hold head of the plug when pull out (grab tail cable is forbidden).

4.2 Startup and shut down direction

1). Turn on power switch of host computer first, then turn on monitor and system switch, now the light source of video camera is on, wait for a little while when microcomputer starts up. Then the monitor plays WINDOWS interface.

2). Double click “Colposcope” icon, choose “new case” and it will show the image shoot by video camera and patient’s information dialog box immediately. (Please read “Instruction of the digital electronic colposcope software” carefully).

3). Shut down: Click “exit” to back to WINDOWS interface, then open “Start” menu to chose “shut down”, chose it and the whole system can be shutdown.

Notice: Never make power-off to shut down unless system halted or other special situation happened.

4) Pull off the outer power plug to make sure the machine separated from power supply, and then cover the covering cloth.

Chapter 5 Instruction

5.1 Examination method

1). Turn on the apparatus to ensure “image set up” is under real-time display status.

2). Specimens before 24 hours, prohibit any vaginal stimulation, such as sexual intercourse, vaginal examination, and local irrigation, pesticides, so as not to affect the results of the inspection. Any inflammation should be controlled first.

3). Make subjects get dorsosacral position, use vaginal dilator to expose cervix (do not use lubricants in order to avoid affecting the observation)

4). Use cotton balls with normal saline to wipe out cervical secretions (inunction can not be forced, so as not to prevent bleeding that may affect the observation)

5). Cameras will be moved away from the cervix about 15-20CM, genital distance about 5-10cm, adjust focal length to enlarge image to observe.

6). Sometimes in order to further distinguish the contraction of blood vessels respond between the surface of cervical squamous cell or columnar epithelium to determine the nature of the Cervical lesions on the surface, the surface of the cervix to be applied in a number of medicines in order to make the image more clearly and more conducive, which must good for diagnose. For example:

●3% acetum: after use this most common solution on cervix, the columnar epithelium rapidly goes to be edema, white, and showing a typical "grape cluster" form, but not

squamous cell, so there is very clear common border between squamous and columnar, it also can be seen by the 3% acetum after the first contraction of blood vessels and then expansion, and also can be seen at or spiral-shaped vessel, but after a few seconds it gradually blurred; the around squamous cell of opening goes white, appears in "crater ".

●Iodine test: use sterile cotton balls to wipe the surface cervical mucus, and then use a small cotton ball dipped with iodine solution to evenly coated dome cervical down. Any pigmentation means negative test, because the normal vaginal or cervical squamous cell contains a wealth of glycogen, painted iodine can be turned into brown; no pigmentation means positive test, for it mainly happened with normal cervical pipe epithelium, surface erosion in coverage column epithelium, squamous cell epithelial dysplasia or cancer. Postmenopausal women because of estrogen levels drop, glycogen content reduced, which may cause sometimes there can be no pigmentation or light pigmentation, so iodine is not a test of cancer-specific screening tests.

●40% -50% of Trichloroacetic (TDA): after smear trichloroacetic, condyloma accuminatumacid will appear thorn-like pop or rod-like processes with clear limits of normal mucosa, pseudocondyloma accuminata mucosa will turn to white after using TDA and surface appear clear rugged and rough.

● Check a suspicious site, get biopsy to have pathology examination.

5.2 All instrument and medicine needed for vagina inspecting

1). Speculum

In colposcope examination, the most common checked site is cervix. Preparing various speculums is suggested to ensure expose cervix in good condition due to different age, height and stature of patients. Large-size one should be used to tall, obesity and vaginal looseness patients. Middle and small size should be used to thin or post-menopausal patients. Speculum should be selected in line with the principle of open field of vision, cervix and vagina can be fully exposed the inside wall is not prominent, so it’s easy to observe, shooting and operation.

Metal speculum is easy to use with superior surface finish, but the disadvantage is reflective of a strong impact on photographs, often make some of the photos appear strong spot, affecting the quality of the photos. If the speculum can be in the side plating into a dark, observation and photography will be much better.

Plastic speculum, the advantage of lower prices to avoid cross-infection, but the exposed field of vision isn’t wide enough and it also have some reflective.

To some of the obese and extremely post-menopausal patients even if use large speculum cervix can not be fully exposed, it would need to use four-leaf retractor.

Some patients with lesions in the neck, can be used to expand neck, neck lesion will be fully exposed for satisfied observation and operation. As for young girls need to

observe the vagina, can draw support devices from E.N.T.department, such as nasoscope.

2). Reagent
In order to distinguish squamous cell and columnar epithelium, and to distinguish normal epithelial and inflammatory or malignant, we often use 3% acetum and iodine solution.

3% acetum

Pure glacial Acetic Acid	3 ml
Distilled water	97 ml

Stored in sealed brown glass bottles for back-up

Iodine solution

Lodine	1 g
Potassium iodide	2 g
Distilled water	100 ml

Stored in sealed brown glass bottles for back-up

40% TCA solution

Pure TCA solution	40 ml
Distilled water	60 ml

Trichloroacetic acid for the treatment of smaller lesions condyloma, and have better treatment for pseudocondyloma.

3). Auxiliary equipment and drugs

Biopsy forceps

Mainly used in the suspicious lesion site to get biopsy forceps for pathological examination. Biopsy forceps length should be about 26 cm, which is more convenient to operate. Biopsy forceps blade should be sharp in order to be able to cut 2 ~ 3mm for the tissue, cut too much will lead to unnecessary bleeding.

Cervical clamps

It should be about 26cm long, the head looks like mouse dens, mainly for fixed traction when super-hard, tough and smooth cervical patients in biopsy examination.

Long curved clamp

It should be 26cm in length, for removing cervical polyps or small submucous myoma.

Articles needed in vaginal drop-off cells examination

Such as: scraper, slide engraved with number, slide cylinder for fixed specimens.

Chapter 6 Precautions

1. Frequency switching of equipment should be avoided otherwise damage will be caused easily.
2. The equipped microcomputer only used for Colposcope system, any damage caused by other application is not included in guarantee range. Equipment damage caused by pirated CD-ROM or using or network interconnection is not included in guarantee range as well.
3. Do not move or shake the equipment when it's turned on. Connect, insert, dismantling or install parts of the instrument is prohibited.
4. The instrument shall be used in clean room with adequate air circulation. Its environment is clean and dry. Don't install the instrument in a location near chemical materials and electric devices with strong electromagnetic and electric fields.
5. Instrument surface is easy to absorb dust due to static electricity, wipe off the power first when you use soft pledget to clean to avoid scratch.
6. Wiping video camera lens with special lens paper.
7. Frequent switching on and off of the instrument shall be prohibited; otherwise it is easy to be damaged. When the instrument is not used, turn off it first, remove the mains plug from the wall socket and cover it with cloth. If the instrument will be not used for a long period of time, please clean and put it into packing box. And don't forget to open box at regular intervals and run the instrument when electricity is turned on (once per month ordinarily).
8. The equipment is packed by carton, and can be transported by air, road and railway.

Chapter 7 Trouble shooting

7.1 Checking

- Check whether power supply is normal, power is connected to host computer and plug is inserted to power source socket.
- Check whether the connection between all the wirings and host computer is normal.

7.2 Trouble shooting

Please see table 1.

Table 1

Symptom	Cause analysis	Shooting Way
Monitor can't work	1. Power switch of monitor isn't on; 2. Computer power isn't turn on; 3. Check power socket; 4. Monitor is out of work。	1. Re-open the switch 2. Put power in good condition 3. Contact manufacturer for maintenance
Printer can't work	1. Check cable connection of printer; 2. Paper use up 3. Check printer type whether it's supported; 4. Printer out of work.	1. Re-connect cable; 2. Paper printer; 3. Re-install drives; 4. Contact manufacturer for maintenance
Print strange characters	1. Whether boot order is correct (open printer power first); 2. Check whether chose right printer type 3. Check cable connection of printer	1、Chose correct printer type; 2、Re-install drives; 3、Re-connect cable.
No image showed in play-zone.	1. Check of video camera power; 2. Check connection between video cable and host computer; 3. Whether open video camera in software.	1、Re-connect cable; 2、Open software video camera.

Chapter 8 Maintenance

- Often check power supply source. If voltage exceed specified range for the instrument(AC 220V～253V), never start the instrument. Use the instrument only after mounting voltage-stabilized source.
- A good grounding power is required, which can improve the safety and anti-jamming capability of the equipment.

- Instruments should be put to avoid humid and dusty environment and corrosion gas and liquid around is prohibited.
- Often check power wire and probe cable of the instrument. Find damage or break and replace them immediately.
- After pulling power plug, clean the appearance of the instrument with absorbent cotton and toothpaste. Never use cleaning agent or germicide with alcohol to wipe it.
- Never open chassis to clean, shake and dismantle internal parts.
- After moving the instrument, check whether the connecting wires between parts are loose. Again properly connect all the wires which are loose.
- If the instrument is out of order, please contact the company or local agent, or can invite experienced technician to examine and repair with the permission of company or agent.

Maintenance of video camera

- Avoid strong-light object, such as: strong light-source and sun, etc.
- Can't located in too-cold or hot place.
- Working environment should avoid dust, damp, water and crashing.
- Away from the radio frequency lines as far as possible, such as audio or video source.

Requirement for transportation and storage:

- Please packed well or covered with dust jacket when you don't use it.
- Please never put equipment in damp and dusty environment.
- Please maintain equipment regularly to keep clean and healthy.
- For equipment is valuables, please avoid shaking or rain.

. Chapter 9 After-sale service

- This product is guaranteed by our company for a period of 18 months. If necessary the company can provide electric circuit diagram, element list. Within

the guarantee period, our company will provide a free repair service for the fault caused by the product quality. After the guarantee period, our company will provide a long-term repair service.

The guarantee shall not apply to any following faults:

a) The faults caused by dismantle and modification carried out by unauthorized people.

b) The faults caused by beat and/or fall during the course of use.

c) The faults caused by non-rational maintenance and/or undesirable environment.

d) The faults caused by misusing counter to this operation manual.

e) The faults caused by repair unauthorized by our company.

f) The faults caused by pirate copy software using or network interconnection.

g) The faults caused by loading software which don't provided by our company or loading other software which don't permitted by us or modifying setting unauthorized.

- The guarantee is not suitable for enclosed free offer.
- The guarantee is not suitable for consumption goods and wearing parts.
- The repair service under the guarantee is provided upon presentation of completed guarantee card delivered with the product.

Jiangsu Sanwe Medical Science and Technology Co.,ltd.

Address: Sanwe Science and Technology Park, Zhujiang Road, Tongshan Economic & Technology Development Zone Xuzhou City, Jiangsu Province Of China.

Tel: (0516) 82308605

Fax: (0516) 82308606

Postal Code: 221116

After-sales service Tel: (0516) 82308605

After-sales service Fax: (0516) 82308606

E-mail: ryan@sanwegroup.com

Website: http://www.vvvmc.com